

### **REMARKS**

This is in response to the Final Office Action mailed July 13, 2006.

Claims 1, 9, 22, 23, and 24 have been amended. Claim 31 has been cancelled. Support for amendments to claims 1, 9, 22, 23, and 24 can be found throughout the originally filed application, e.g., paragraphs 41 and 43, and Table 4. No new matter has been introduced. Independent claim 1 and its dependent claims 2-3, 5-21 and 28-30, independent claim 22 and its dependent claim 23, and independent claim 24 and its dependent claims 26-27 are currently pending and at issue.

#### **Claim Rejections - 35 U.S.C. §112**

Claims 1, 5-10, 22-24 and 28-31 have been rejected under 35 U.S. C. §112, first paragraph, for failing to comply with the enablement requirement. The Examiner asserts that the specification, while enabling for those on a low-calorie diet, does not reasonably provide enablement for one on any diet and consuming any amount of dairy.

The claims have been amended to include the requirement of being on a low-calorie diet.

The Examiner further rejects claim 31 because allegedly the "at least about 102 portions of dairy per month" is not supported in the originally filed application and that the term "portions" is not defined. Claim 31 has been cancelled without prejudice to expedite examination.

Claim 23 has been amended to recite an amount of "102 servings", which is supported in the originally filed specification, e.g., Table 4, column 3, row 2, reciting  $102.8 \pm 3.6$  of dairy consumption, servings/month.

The Applicants respectfully request that these rejections be withdrawn.

#### **Claim Rejections - 35 U.S.C. §103**

Independent claims 1, 22 and 24, have been rejected as obvious under 35 U.S.C. § 103 based on the title "Milk Mustache Campaign" ("Tabbitta"), in view of the article titled "Randomised Controlled Trial of Novel, Simple and Well Supervised Weight Reducing Diets in Outpatients" ("Summerbell"). The Examiner concludes that it would have been obvious to a person of ordinary skill at the time of the application, to know that retailers of calcium-enriched products (such as dairy products), would promote the consumption of the products for a benefit against obesity.

Applicants contend that Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references teach or expressly or impliedly suggest any of the limitations set forth in the present claims, and that there is no motivation to combine these references, which teach away from the claimed invention, and there would be no reasonable expectation of success.

In addition, the Applicants previously submitted evidence showing the present invention's unexpected results, which have led to a significant shift in the scientific community and the food industry, who have supported and endorsed the methods of the present invention, leading to significant recognition and commercial success.

Amended independent claims 1, 22, and 24 are directed to methods of inducing consumption of, promoting or communicating to consumers suffering from obesity that in combination: (1) consuming dietary calcium from calcium-containing products or dairy in an amount that is above suboptimal, e.g., 773 mg of calcium per day or about 57 servings of dairy per month, over a period of time, and (2) maintaining a restricted caloric diet below ad lib in a range that is about 200 kcal to about 2500 kcal per day, during that period of time, has benefits on body weight or body fat from the consumption of the dietary calcium from the calcium-containing product or dairy product, in inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual.

Applicants contend that the present invention is distinct from all the cited references because none of the cited or applied references, either alone or in combination, disclose, teach or suggest the methods of independent claims 1, 22, and 24.

Tabbita discloses the promotion of milk for its beneficial effects on osteoporosis, not weight-related conditions, and the attempt of the dairy industry to market milk as being "cool", not as an agent producing weight-related benefits. Furthermore, Tabbita emphasizes the declining interest in the consumption of milk, attributing it to the perception that milk has a high fat content, and that when the fat content is removed, then the milk no longer contains beneficial vitamins and minerals, except for the calcium for osteoporosis. This statement would lead one away from the

teaching of the present invention, which involves the use of dietary calcium or dairy, to directly induce weight loss or other weight-related effects.

Tabbita does not teach or suggest, as in amended claims 1, 22, and 24, that in combination, (1) consuming dietary calcium from calcium-containing products or dairy in an amount that is above suboptimal, e.g., 773 mg of calcium per day or about 57 servings of dairy per month, over a period of time, and (2) maintaining a restricted caloric diet below ad lib in a range that is about 200 kcal to about 2500 kcal per day, during that period of time, has benefits on body weight or body fat. Nor does Tabbita teach or suggest that the benefits on body weight or body fat are from the consumption of the dietary calcium from the calcium-containing product or dairy product, in inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual.

Moreover, Applicants contend that Summerbell does not disclose, teach or suggest any of the elements of independent claims 1, 22 and 24, nor cure the defects of Tabbita.

As set forth in the introduction, Summerbell tests diets with high compliance and hence good for weight loss. The study in Summerbell was designed to test the hypothesis that prescription of a simple and novel diet would result in higher levels of compliance and weight loss. Summerbell associates higher weight loss for the milk groups diet because that diet is "simple but much less boring and patients were more likely to comply with it" than with the conventional diet. Indeed, Summerbell is "not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall." Summerbell concludes that "[p]robably the best strategy is to rotate diets..." This statement would lead one away from the teaching of the present invention, which involves the use of sufficient amounts of dietary calcium or dairy, e.g., daily for a month or substantially longer. The point to extrapolate from Summerbell is that one could use any type of food regimen or diet so long as it is simple and less boring to ensure compliance. Nowhere in Summerbell is it disclosed that calcium or dairy alone directly induces weight loss, reduces weight gain, and/or increases the metabolic consumption of adipose tissue in the individual, as opposed to indirectly causing a dieter to lose weight by reducing overall caloric intake.

Also, Applicants have submitted evidence showing that due to the unexpected results of Dr. Zemel's work, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The evidence shows that the invention has achieved considerable public recognition and commercial success.

Therefore, Tabbita or Summerbell, either alone or in combination, do not disclose, teach or suggest the claimed invention as set forth in claims 1, 22, or 24. Nor do they teach or suggest the subject matter of dependent claims 2-3, 5-21, 23, and 24-30, which include additional limitations distinguishing them from the cited references.

The Examiner further rejects claim 21, as being obvious based on Tabbita and Summerbell, in further view of Christiansen, which teaches a trademark calcium-fortified product. However, Christiansen refers in example 4 to a cereal containing a particular brand of calcium chelate, but does not describe communicating a trademark for a calcium-containing product for its weight-related effects as recited in the present claims. Christiansen does not disclose, teach, suggest, or cure the defects of Tabbita or Summerbell, as discussed above for claim 1.

Moreover, the Examiner rejects claims 28-31, as being obvious based on Tabbita and Summerbell, in further view of the article titled "Jones Sports Mustache for Milk", which teaches that three glasses for milk a day, about 1 gram of calcium, is a good way of getting bone-strengthening calcium. This reference does not disclose, teach, suggest or cure the defects of Tabbita or Summerbell, as discussed above for claim 1.

Claims 1-3, 5-24 and 26-30 are patentable because none of the cited references or material disclose, teach or suggest the present invention. Applicants respectfully request these rejections be withdrawn.

### **Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request

that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-3, 5-24 and 26-30 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: October 13, 2006

Respectfully submitted,

By 

Michael A. Gollin

Registration No.: 31,957

Zayd Alathari

Registration No.: 42,256

VENABLE LLP

P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant

#792983